REMARKS

In the Office Action dated November 19, 2007, claims 21-42 were provisionally rejected on the basis of non-statutory obviousness-type double patenting over claims 27-49 of Co-Pending Application Serial No. 10/562,181. A Terminal Disclaimer is submitted herewith that overcomes this rejection.

Claims 21, 22, 26-29, 31-34, 35, 38-40 and 42 were rejected under 35 U.S.C. §102(e) as being anticipated by Baumann et al. Claims 24, 25, 36 and 37 were rejected under 35 U.S.C. §103(a) as being unpatentable over Baumann et al.

Claims 23, 30, 32 and 33 were stated to be allowable if rewritten in independent form.

The above rejections are traversed in view of the amendments that have been made to independent claims 21, 31 and 34, and therefore claims 23, 30, 32 and 33 have been maintained in dependent form at this time.

The implantable medical apparatus, the cardiac pacemaker and the method disclosed and claimed in the present application are for the purpose of providing an early status indication of diastolic heart failure (DHF). As summarized in the introductory portion of the present specification, and as explained in more detail in the article by Kitzman et al. that is of record herein as Reference AT in the Information Disclosure Statement filed June 9, 2006, DHF is not the same as congestive heart failure (CHF), and is more difficult to detect or predict. In the subject matter disclosed and claimed in the present application, an indicator of the DHF status of the heart of a subject is generated by determining a current workload of the subject, and measuring the magnitude of pulse pressure of the subject. The magnitude of pulse pressure is then compared with a threshold value that has a

predetermined association with the current workload as a DHF predictor. A comparison result is thereby generated that indicates the DHF state of the heart of the subject.

The Baumann et al. reference does not disclose any specific techniques for identifying or detecting DHF, and merely provides a general assessment of the hemodynamic operation of the heart of a subject, so as to optimize lead placement for the subject. As stated in the paragraph beginning at column 1, line 17, the purpose of the optimized lead placement in the Baumann et al. reference is for the purpose of improving the hemodynamics in congestive heart failure patients, but there is no teaching or disclosure in the Baumann et al. reference as to how to detect or identify CHF in the first place. It is simply assumed that the lead optimization procedure will be applied to a patient who is exhibiting CHF, and then an optimized lead placement configuration can be identified as being the configuration that produces the most favorable measured hemodynamics. Therefore, even in the context of CHF, there is no detection algorithm disclosed or suggested in the Baumann et al. reference. The Baumann et al. reference is therefore even farther removed from disclosing any sort of detection procedure for DHF.

Moreover, the Examiner stated that Baumann et al. define pulse pressure as the difference between peak systolic aortic pressure and end-diastolic aortic pressure. The Baumann et al. reference at column 1, lines 26-29 states that pulse pressure defined in that manner *could* be used to optimize the pacing parameters in applying CHF therapy, but a direct measure of the pulse pressure would require the use of a suitably positioned pressure sensor inside the heart. As an alternative to using such a pressure sensor, the Baumann et al. reference uses an *indirect*

indication of pulse pressure, which is derived from the patient's atrial cycle length (ACL), as stated at column 1, lines 30-32. As is clear from the remainder of the Baumann et al. disclosure, although the ACL may be a reliable *indicator* of the pulse pressure, by being correlated therewith, it is not the same, as acknowledged by Baumann et al., as making a direct measurement of pulse pressure. Moreover, since the actual magnitude of the pulse pressure is immaterial to the analysis disclosed in the Baumann et al. reference, which only makes use of *changes* in the pulse pressure, the use of the ACL as an indicator of pulse pressure is sufficient, rather than making a direct measurement of the magnitude of pulse pressure. This is explained at column 5, lines 42-58 of the Baumann et al. reference. Baumann et al. are only interested in detecting the *change* in the ACL, and it is known that this change in ACL has a physiological correlation to a *change* in the pulse pressure. Nevertheless, there is no actual measurement of the magnitude of pulse pressure that is made in the Baumann et al. reference, because this is immaterial to the type of analysis that is undertaken in the Baumann et al. reference.

Moreover, as noted above it is important, in order to make use of the measured magnitude of pulse pressure for the purpose of identifying a DHF state of the heart, to obtain that pulse pressure magnitude measurement at a workload of the patient that can be identified, because the magnitude of the pulse pressure must be then compared to a predetermined reference value that has a predetermined association with the current workload as a DHF predictor. This underlying theory is explained in the aforementioned Kitzman et al. article. By statistical analysis of a patient population, predetermined relationships can be ascertained between the pulse pressure, at respectively different workloads, and the propensity or likelihood

that DHF is present if the measured magnitude of pulse pressure at the particular workload exceeds a predetermined threshold that is associated with that pulse pressure at that workload.

No such comparison is disclosed or suggested in the Baumann et al. reference, because no such comparison is necessary for the purpose of the optimized lead placement with which the Baumann et al. reference is concerned.

Each of independent claims 21, 31 and 34 has been amended consistent with the above discussion, and for the above reasons Applicants submit that none of those claims is anticipated by Baumann et al. For the same reasons, none of the claims respectively depending from those independent claims is anticipated by Baumann et al.

The same considerations are applicable to the rejection of claims 24, 25, 36 and 37 as being obvious in view of Baumann et al. Since there is no teaching or suggestion whatsoever in the Baumann et al. reference regarding identifying a DHF state of the heart of a subject, none of those claims would have been obvious in view of the teachings of Baumann et al.

Lastly, as noted above the Kitzman et al. article was submitted as one of the references (Reference AT) in the Information Disclosure Statement that was filed on June 9, 2006, and this is the four page "NPL document" that is present in PAIR for this application, with the mailroom date of June 9, 2006. Due to an oversight, however, Reference AT was not listed on Form 1449 that was submitted with the Information Disclosure Statement, and which was initialed by the Examiner. Therefore, another Form 1449 is submitted herewith, on which the Kitzman et al.

article is listed by itself as Reference AT. The Examiner is requested to initial this additional Form 1449 to indicate consideration of Reference AT.

All claims of the application are submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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Form PTO-1449								
INFORMATION DISCLOSURE CITATION IN AN APPLICATION (use several sheets if necessary)							Docket No. P05,0366	Serial No. 10/562,109
							Applicant Sven-Erik Hedberg et al	
							Filing Date December 22, 2005	Group Art Unit 3738
U.S. PATENT DOCUMENTS								
Examiner's Initials		Document Number	Date	Name	Class	Subclass	Filing Date If appropriate	
	AA							
	AB							
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	AF							
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							Yes	No
	AL							
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	AT	"Pathophysiological Characterization of Isolated Diastolic Heart Failure in Comparison to Systolic Heart Failure," Kitzman et al, Journal of the American Medical Association, Vol. 288, No. 17 (November 6, 2002), pages 2144-2150						
	AU							
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